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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
12/21/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@rosenbaumsilvert.com

Office Action Summary	Application No. 09/707,685	Applicant(s) PALMAZ ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *39-53 and 67-74* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *39-53 and 67-74* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2012 has been entered.

Response to Arguments

Applicant's arguments filed December 3, 2012 have been fully considered but they are not persuasive.

It is also noted that applicants specification admits that the material properties (including precipitates) "are *achieved* by fabricating a stent by the same metal deposition methodologies as are ***used and standard*** in the microelectronics and nano-fabrication vacuum coating arts", pg.11, lines 10-15. These "used and standard" deposition methods are the same methods disclosed and referred to in Whitcher. Thus it seems inherent since the same methods are used (including the same pressures used, see Whitcher examples 1-5), the same material properties (including minimized precipitates) will be *achieved* by Whitcher.

Further, the applicant admits that the vapor/vacuum deposition processes of nickel titanium eliminate the need to control precipitates, since no precipitates exist in the deposited film (see pg.14, lines 19-30). "Vapor deposition of the inventive endoluminal stent..significantly

reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material. It is common practice in the nickel-titanium endoluminal device industry to control transition temperatures and resulting mechanical properties by altering local granular nickel-titanium ratios by *precipitation regimens*. In the present invention, *the need to control precipitates for mechanical properties is eliminated.* Where nickel-titanium is employed as the stent-forming metal in the present invention, local nickel-titanium ratios will be the same or virtually identical to the nickel-titanium ratios in the bulk material, while still allowing for optimal morphology and *elimination the need for employing precipitation heat treatment*." This disclosure admits that by using standard vapor/vacuum deposition methods of nickel titanium, there is not need to anneal (heat treat) the finished product to remove precipitates, since no precipitates are formed during the deposition process. Again, since Whitcher uses the same standard deposition methods disclosed by applicant, deposition of the same material Ni-Ti and does not anneal/heat treat in some embodiments, no precipitates exist in the Whitcher's stent, thus Whitcher is inherently minimizing the formation of precipitates just as applicant is.

Also, applicant's specification admits that standard deposition methods produce the material properties desired and does not limit the deposition to any particular process parameters for reducing precipitates.

The applicant has argued that Whitcher does not disclose a process condition selected from chamber pressure, deposition pressure, or partial pressure of process gas optimized to minimize formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing

precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected*. A user selects these parameter to effect a certain outcome, thus the selection is considered to optimize since Whitcher discloses the purpose is to improve properties (P0001, P0008) by tailoring the parameters (P0062, P0028). What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). Whitcher discloses in examples 1-5 a chamber pressure of 10-6 Torr and a deposition pressure of 10 milliTorr, both which encompass pressures supported by applicants disclosure as optimal process conditions for the desired effect (see incorporated by reference 09/443,929, now US Pat 6,379,383). As Whitcher is using the same pressures as applicant, it may be assumed the same result would occur in Whitcher as would with applicants claimed process-minimized precipitates. Applicant has argued that it is not the vacuum deposition process generically that minimizes precipitates, but instead the optimization of a specific process parameter such as chamber and deposition pressure. If this is the case, since Whitcher discloses the same chamber and deposition pressure used to deposit the same material as applicant, it is assumed the same result will occur-minimized precipitates.

In summary, it is the examiners position that applicants do not claim any specific process pressure parameters numerically to product a specific numerical amount of precipitates. It instead appears by the applicants specification that basic known vacuum deposition processes used for a long time in the microelectronic arts are what are being used to optimize properties (to no specific extent) in stent manufacturing. Whitcher is doing exactly this, using known vacuum deposition processes once used in the microelectronic arts, and applying them to stent manufacturing with use of materials such as nickel and titanium, the same materials and processes disclosed by applicant and admitted by applicant to be previously known and used. The outcome or final product is assumed by the examiner to be the same as applicant has not claimed process parameters any different than that used in Whitcher or in standard microelectronic deposition arts. The only mention of defined process parameter of chamber pressure, deposition pressure and partial pressure are in applicants incorporated by reference application 09/443,929, now US Patent 6,379,383 which gives an example of 2x10-7 Torr chamber pressure and 0.1-10 milliTorr deposition pressure (which happen to be the same pressures disclosed and encompassed by Whitcher), however it is noted that these pressure are not disclosed to specifically minimize precipitates, but just to optimize properties generally.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the appellant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the appellant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited previously). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the applicant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions including chamber pressure, deposition pressure or partial pressure of process gas (P0035, P0036, P0037; example 1), the process condition (pressure) optimized to minimize the formation of chemical and intra and inter-granular precipitates (Whitcher discloses that *tailoring* P0028 and customizing the process parameters results in *improved* material properties overall, P0062, P0001, P0008; Whitcher discloses selecting an appropriate chamber pressure, thus this is considered optimizing; also it is noted that although applicant claims selecting a pressure to optimize properties such as minimizing precipitates, and argues that it is the process parameters such as pressure that really determines the material properties (precipitates) and not the vacuum deposition process as a whole, the applicant does not disclose any specific numeric pressures that would be considered optimal. Thus, what is an optimized pressure is vague and indefinite. The only reference to a pressure, would be through the incorporated by reference serial number 09/443,929, now US Patent 6,379,383, which gives examples of a chamber

pressure of 2x10-7 Torr and deposition pressure of 0.1-10 milliTorr. Taking this into consideration, the pressures disclosed by Whitcher in all of examples 1-5 include chamber pressures of less than 10-6 Torr, which includes applicants pressure range; and Whitcher also discloses a deposition pressure of 10milliTorr, which falls also within 383' pressure range; thus since Whitcher is using the same pressures as the applicant, it may be assumed that Whitcher pressures would have the same result-minimized precipitates-as the result of applicants specified pressures) in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR *a crystalline film*, see P0038-P0040, P0043, P0049, P0061, example 1), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process pressure condition "optimized to minimize" granular precipitates; granular precipitates are categorized in the applicant's specification as one of the many "material properties" that are collectively controlled by deposition, see pg.10, lines 12-16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates* and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037), selection of conditions (temp, pressure, rate, etc. specifically, the same

chamber pressure and deposition pressure used by applicant, thus if applicant considered 2x10-7 Torr and 10milliTorr to be optimal pressure for minimizing precipitates, then if Whitcher is using these same pressure, see Whitcher examples 1-5, it is assumed Whitcher's process will have the same result of minimized precipitates and Whitcher's pressure is considered "optimized" since it is the same as applicants pressure and applicant considers this pressure optimized) and the use of the same materials used by the applicant (Whitcher P0062), and discloses such processes control material properties (P0011, P0028), therefore, inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Also, Whitcher discloses selection to *improve* mechanical properties (P0001, P0008, P0048, P0062, P0066), thus the process conditions may be

considered to be "optimized" since the purpose is to improve properties. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled/optimized by the *selection and tailoring to improve properties*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc. to their preference (optimal).

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, applicant has claimed "process conditions..optimized to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized" or to "optimized". It is vague and arbitrary what amount "minimize" is and how it should be measured/examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, and no annealing step is required, the film would have no precipitates.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [P0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [P0034, P0035, P0036, P0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([P0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([P0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [P0034, P0035, P0036, P0037] nickel and titanium [P0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [P0066, 55.9 is not less than 51.5], table 1, the deposition occurring under process conditions selected from chamber pressure, deposition pressure, and partial pressure of process gas, the condition optimized to minimize the formation of granular precipitates (Whitcher discloses that *tailoring* P0028 and customizing the process parameters results in *improved* material properties overall, P0062, P0001, P0008; Whitcher discloses selecting an appropriate chamber pressure, thus this is considered optimizing; also it is noted that although applicant claims selecting a pressure to optimize properties such as minimizing precipitates, and argues that it is the process parameters such as pressure that really determines the material properties (precipitates) and not the vacuum deposition process as a whole, the applicant does not disclose any specific numeric pressures that would be considered optimal. Thus, what is an optimized pressure is vague and indefinite. The only reference to a pressure, would be through the incorporated by reference serial number 09/443,929, now US

Patent 6,379,383, which gives examples of a chamber pressure of 2x10-7 Torr and deposition pressure of 0.1-10 milliTorr. Taking this into consideration, the pressures disclosed by Whitcher in all of examples 1-5 include chamber pressures of less than 10-6 Torr, which includes applicants pressure range; and Whitcher also discloses a deposition pressure of 10milliTorr, which falls also within 383' pressure range; thus since Whitcher is using the same pressures as the applicant, it may be assumed that Whitcher pressures would have the same result-minimized precipitates-as the result of applicants specified pressures) in the bulk material of a deposited tubular unpatterned crystalline film (P0038-P0040, P0043, P0049, P0061, example 1), and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "optimized to minimize" granular precipitates, granular precipitates are categorized in the applicant's specification as "material properties" and are part of the microstructure see pg.10, lines 12-16. The applicant's specification discloses that the material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, inherently Whitcher is controlling/optimizing and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028,

0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled and optimized, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled and optimized* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled and optimized by the *selection*. Especially since Whitcher has disclosed use of the same pressures as applicant has supported as being optimal. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

As applicant's specification points out, pg.14, lines 19-30, if deposition processes are used for nickel titanium alloys, there is no need to control the precipitates as there are not any in the deposited film. No annealing is required. The specification also points out that it is the vapor deposition process that significantly reduces or virtually eliminates the precipitates. Thus if it is the deposition process alone that reduces the presence of precipitates, Whitcher inherently reduces the presence of precipitates in the performance of the same standard deposition methods disclosed by applicant.

Also, applicant has claimed "process conditions... optimized to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition and Whitcher used the same pressures applicant is considering to be optimizing.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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